UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,904	11/30/2001	Harold R. Garner	119929-1037	4132

34725 7590 01/03/2007

CHALKER FLORES, LLP
2711 LBJ FRWY
Suite 1036
DALLAS, TX 75234

EXAMINER	
MORAN, MARJORIE A	
ART UNIT	PAPER NUMBER
1631	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/03/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/998,904	GARNER ET AL.	
	Examiner	Art Unit	
	Marjorie A. Moran	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9-42,44-53 and 56-213* is/are pending in the application.

4a) Of the above claim(s) *11,13-21,23-36,58-202 and 205-213* is/are withdrawn from consideration.

5)☒ Claim(s) *203* is/are allowed.

6)☒ Claim(s) *1-4, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, and 204* is/are rejected.

7)☒ Claim(s) *57* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/10/06 has been entered.

Claims 1-3, 5-7, 9-42, 44-53, and 56-213 are pending.

Election/Restrictions

Claims 11, 13-21, 23-36, 58-202, and 205-213 are again withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in a paper filed 11/3/03. Applicant is assured that upon a finding of allowability of a generic claim, claims directed to nonelected species will be rejoined and examined.

An action on the merits of elected claims 1-3, 5-7, 9-10, 12, 22, and 37-42, 44-53, 56-57, 203 and 204, as they read on the elected species, follows.

All rejections and objections not reiterated below are hereby withdrawn.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 2a, 2b, and 2c. The specification on page 5 refers to Figures 2A-2C, and describes Figures labeled 2a, 2b, and 2c; however, Figure 2 does not contain anything labeled as 2a, 2b, or 2c. Corrected drawing sheets in compliance with 37 CFR 1.121(d) or appropriate amendment to the specification is/are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 57 is objected to because of the following informalities: the phrase "is determined" in line 4 would be clearer if amended to "is performed". It is apparent that applicant intends to limit the comparing step of claim 1 to one which is performed in silico, but the phrasing is awkward. Appropriate correction is requested.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, and 57 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are directed to a method for predicting locations of one or more SNPs in a nucleic acid sequence wherein the method comprises only steps of mathematical manipulation. None of the steps recited in the claims results in a physical transformation of matter. Where a claimed method does not recite or result in a physical transformation of matter, the claim may be statutory where it recites a tangible, concrete, and useful result. The instant claims do recite a concrete and tangible result; i.e. the locations of possible SNPs; however, this result is not presented, "output," or otherwise communicated to a user in a tangible form, therefore the claims fail to recite a concrete, useful and tangible result, and are not statutory. For a further explanation of statutory subject matter, applicant is directed to MPEP 2106, especially section IV. Applicant is advised that guidelines with regard to statutory subject matter have changed and that this rejection is made in view of the new guidelines. Applicant is strongly encouraged to contact the examiner if there is any confusion regarding this rejection and the guidelines as now set forth in MPEP 2106.

It is noted that as claims 203 and 204 are clearly directed to products, they recite statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, and 204 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites a step of identifying "locations of the nucleic acid sequence" where SNPs are likely to occur. It is unclear what "locations" for the nucleic acid are intended; i.e. locations within a particular cell, or a selected tissue, or within a cell type (e.g. a transformed or recombinant cell), therefore the claim is indefinite. It is recognized that the confusion may arise due to a typographical error. However, if applicant intends to identify (base or codon) locations WITHIN the nucleic acid sequence where SNPs are likely to occur, then this is not clear from the current claim language. Even if one were to assume that this is what is intended, it is still unclear what sort of "locations" within the nucleic acid sequence are intended; i.e. a single base which may BE a SNP, or a codon within which a SNP may occur. The examiner recommends that applicant clearly set forth what is intended by a "location."

Claim 2 limits the method of claim 1 to "further" comprise one or more nucleic acid sequences with chemical modifications. It is unclear what relationship the chemically modified nucleic acids are intended to have with any element or step of claim 1. For example, it is unclear whether SNP "locations" are to be identified for chemically modified nucleic acids in addition to the nucleic acid sequence recited in claim 1, or in

place of the nucleic acid sequence of claim 1, or perhaps whether chemically modified nucleic acid sequences are to be used in calculating/generating a variation frequency and/or matrix. As it is unclear where the chemically modified nucleic acid sequence(s) of claim 2 are intended to "fit" into the method of claim 1, claims 2 and 3 are indefinite.

Claim 3 recites the phrase "the individual nucleic acid bases" in line 4. The phrase lacks antecedent basis, therefore claim 3 is indefinite. It is also unclear which of the nucleic acid sequences of claims 1 and/or 2 are intended to be the one(s) comprising the affected "individual... bases," therefore the claim is further indefinite.

Claim 3 recites the phrase "the nucleic acid sequence" in line 4. It is unclear whether the nucleic acid sequence of claim 1 or the chemically modified nucleic acid sequence(s) of claim 2 are intended to be the antecedent basis of the phrase, therefore claim 3 is indefinite.

Claims 5 and 6 recite the term "the variation," each in line 1. The phrase lacks antecedent basis in the claims, therefore the claims are indefinite.

Claim 10 recites the phrases "the individual nucleic acid bases" and "the nucleic acid sequence" in line 4. Parent claim 9 limits a *dataset* to comprise *genes* with chemical modifications, thus claim 9 is interpreted to limit the DATA in the dataset to comprise information with regard to genes which have been chemically modified. Parent claim 9 does not recite any nucleic acid sequences or individual bases to be those which are chemically modified. It is recognized that genes comprise sequences; however, the DATA which is limited to comprise information concerning chemical modification of genes does not necessarily comprise information with regard to

chemically modified *sequences*. However, claim 1, from which claim 9 depends, does recite a nucleic acid sequence for which SNP locations are identified. Claim 1 does not recite any individual nucleic acid bases. Thus, it is unclear just what is intended to be limited by claim 10, and claim 10 is indefinite.

Claim 12 recites that the variation frequency "is determined" from a known mutation dataset. It is unclear whether applicant intends to further limit a method step or intends to limit the dataset from which the variation frequency is calculated. If the former, then it is unclear whether the "determining" is intended to be a different step from that of "calculating" in claim 1, is intended to supplement the calculating step, or is intended to replace the calculating step. If applicant intends an active method step, then such a step should be recite in active, positive terms. If applicant intends to limit a dataset, then it is further unclear whether applicant intends to limit the "dataset of two or more genes" recited in claim 1 to be a known mutation dataset, or intends a different dataset. If applicant intends to limit the dataset, then the claim should be rewritten to clearly reflect the limitation intended. An example of acceptable claim language follows:

--The method of claim 1, wherein the dataset of two or more genes is a known mutation dataset.--

It is noted that this is merely an example of acceptable claim format, and is not intended to be a suggestion for actual claim limitations, as it is unclear just what limitations are intended. Any amendments should clearly reflect *applicant's* intended limitations and must be fully supported and enabled by the originally filed disclosure.

Claim 22 recites that the variation frequency "is adjusted" for wild type genes. It is unclear if the "adjustment" is intend to be a method step or a limitation of the variation frequency; i.e. one which has been "adjusted." If the former, then applicant is reminded that claim steps should be recited using active, positive claim language; e.g. "The method of claim 1, further comprising adjusting the variation frequency...." In addition, it is unclear where in the method of claim 1 this step is intended to occur. If the latter, then it is further unclear what limitation of the claimed METHOD is intended by limiting the DATA which results from a method step.

Claim 45 recites that a variation predictiveness matrix "correlates" a frequency of codon mutations "with a variation predictiveness value ...from one to ten bases at a time." This combination of phrases is nonsensical as a matrix can not actively "correlate" anything. A matrix is merely data, not a program or algorithm or "instructions" for performing a correlation. The "correlates" phrase may reasonably be interpreted to mean that the matrix is one wherein a first codon mutation is correlated to a second codon mutation. However, then lines 3-4 of the claim do not make sense. It is unclear WHAT is to be performed (or correlated) "with a variation predictiveness value from one to ten bases at a time." As the limitation(s) intended are unclear, the claim is indefinite.

Claim 46 recite that a variation predictiveness matrix "is normalized." Claims 47, 48 and 56 recite that the matrix "is generated" or "is determined" from a mutant dataset/database. It is unclear whether these phrases are intended to be method steps of merely limitations of the matrix and/or data within the matrix. If the former, then it is

further unclear when in the method of claim 1 these steps are intended to occur. If the latter, then is further unclear what limitation of the method is intended by limiting data resulting from a method step. See above for examples of clarifying claim language.

Claim 52 recites that a matrix "is based on" a mutant gene dataset. The relationship intended between the matrix and a mutant gene dataset is unclear; i.e. it is unclear whether the dataset from which a variation frequency is calculated (and from which the matrix is generated) is intended to be a mutant gene dataset or whether the matrix is intended to encompass data from variety of datasets, wherein at least part of the data comprises information regarding mutant genes, or if some other relationship between the matrix and a mutant dataset are intended. As the limitation(s) intended for a matrix and/or dataset are unclear, the claim is indefinite.

Claim 204 recites a program for predicting one or more locations of polymorphisms in the preamble, but does not recite any actual step/instruction of predicting polymorphism locations. The claim does recite a final step of predicting locations where a variation is likely to occur in one or more codons; however a "variation" in a codon is not necessarily a polymorphism. For example, a "variation" which results in a stop codon is generally regarded as a mutation, not necessarily a polymorphism. See paragraph 20 of the specification, which specifically defines mutations. The instant specification does not define a polymorphism, but those skilled in the art generally understand a polymorphism to be one which results in allelic "variance" (e.g. differing forms of a gene): i.e. a polymorphism is a specific type of variance or mutation. As it is unclear whether the program is actually intended to

predict locations of polymorphisms, or to predict locations of variations or mutations (broadly), the claim is indefinite.

In order to facilitate prosecution, the examiner performed a cursory review of nonelected claims and noted that many nonelected claims recite claim language similar to that rejected above; e.g. in claims 12, 22 and 46. It is recommended that applicant review the claim language of nonelected claims, and amend appropriately, in order to expedite allowance should these claims be rejoined.

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection set forth above.

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance: the amendment filed 10/10/06 overcomes the rejections of record for claim 203. The prior art does not teach or fairly suggest a program on a computer readable medium comprising code for predicting locations of variations in a wild-type gene sequence by generating a variation predictiveness matrix from calculated variation frequencies and comparing the wild-type sequence, one or more groups at a time, to the matrix to thus identify locations of likely base variations in the wild-type sequence.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claim 203 is allowed; claims 1-4, 5-7, 9, 10, 12, 22, 37-42, 44-53, 56, 57, and 204 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Monday-Friday; 6 am-2:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
12/22/06